K120164

JUN - 8 2012

510(k) Summary

PROTEUS™ PTA Catheter with Embolic Capture Feature

Introduction

This document contains the 510(k) summary for the modified PROTEUS™ PTA Catheter with Embolic Capture Feature. The content of this summary is based on the requirements of 21 CFR Section 807.92(c).

Applicant Name and Address:

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Summary Preparation Date: 1/18/2012

Device Name and Classification:

Trade Name:	PROTEUS™ PTA Balloon Catheter with Embolic Capture Feature
Common Name:	Percutaneous Transluminal Angioplasty Balloon Catheter
Classification Name:	Catheter, Percutaneous
Classification:	Class II, 21 CFR 870.1250
Product Code	DQY/LIT

Predicate Devices:

The modified PROTEUS™ Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter with Embolic Capture Feature is claimed to be substantially equivalent to the following legally marketed predicate device:

- Angioslide PROTEUS™ PTA Balloon Catheter with Embolic Capture Feature (K111750)

Performance Standards: There are no mandatory performance standards for this device.

Device Description (see Figure 1)

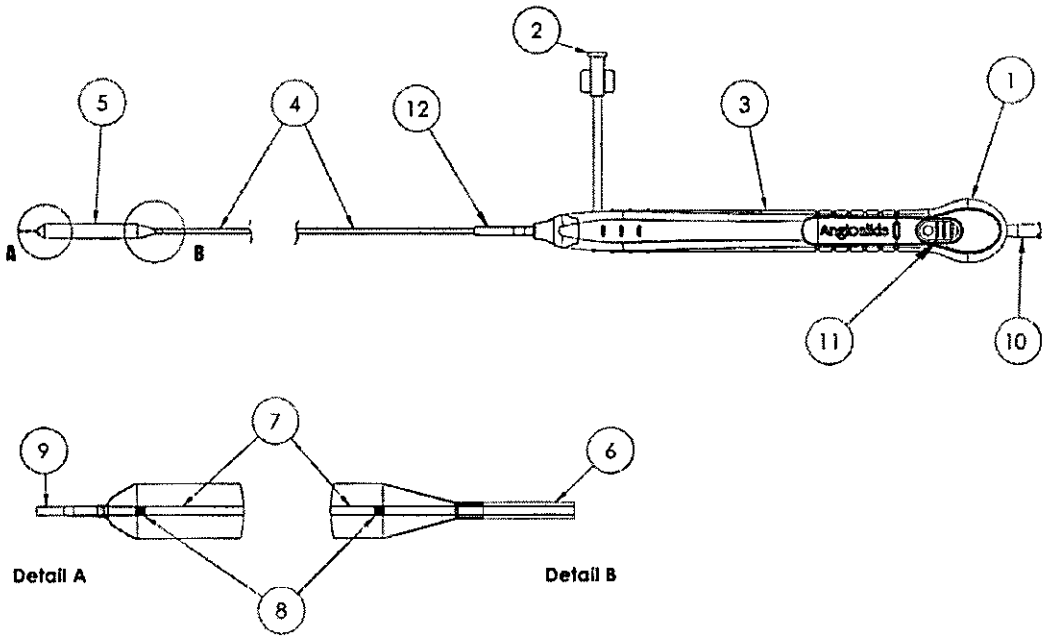

Figure 1

The Angioslide PROTEUS™ Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter with Embolic Capture Feature is an over the wire dual lumen catheter with a foldable balloon (5) located near the distal atraumatic soft tip (9).

One lumen is used for inflation of the balloon and is accessed via the inflation port (2). The other lumen, starting at the guidewire port (10), allows access to the distal tip for guidewire insertion (max. 0.035"). The balloon has two radiopaque markers (8) for positioning the balloon relative to stenosis. The radiopaque markers indicate the dilating section of the balloon and help in balloon placement. The balloon is designed to provide an inflatable segment of known diameter and length at specified pressure.

The shaft (4) comprises the outer shaft (6) and the inner shaft (7). The distal end of the balloon (A) is connected to the inner shaft and the proximal end of the balloon (B) is connected to the outer shaft. The inner shaft is connected to the proximal hub (10) which is connected to the pulling knob (1) and the outer shaft is connected to the handle grip (3). The pulling knob lock (11) locks the handle grip and the pulling knob together. The distal end of the balloon is folded inwards towards the proximal end of the balloon, by pressing on pulling knob lock (11) and pulling the pulling knob away from the handle (1). The embolic capture feature involves a single-use suction mechanism that works through inward folding of the balloon, which creates negative pressure within the capture cavity for debris capture and removal. The reduced pressure in the capture cavity causes some of the particles that are released during the procedure to flow into the cavity for containment and removal.

The balloon size and diameter are printed on the strain relief (12). Refer also to the package label for information about catheter length, balloon nominal and rated burst pressure, balloon size, balloon compliance, guidewire compatibility and sheath compatibility.

Indications for Use:

The PROTEUS™ Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter with Embolic Capture Feature is indicated for peripheral transluminal angioplasty and for capture and containment of embolic material during angioplasty, for the femoral, iliac, ilio-femoral, popliteal, tibial, peroneal, and profunda arteries.

The PROTEUS™ PTA Balloon Catheter with Embolic Capture Feature is not intended for use in the renal, cerebral, coronary or carotid vasculature.

Comparison of Technological Characteristics

The PROTEUS™ Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter is an over the wire co-axial dual lumen catheter with a foldable balloon located near the distal atraumatic soft tip. The catheter is compatible with a 0.035" guidewire.

The balloon catheter technological characteristics of the PROTEUS™ PTA Balloon Catheter are identical to those of the PROTEUS™ PTA Balloon Catheter (K111750). In both devices, lesion dilation is achieved by means of an inflatable balloon.

The PROTEUS™ PTA Balloon Catheter overall length, catheter sheath sizing, balloon diameter, balloon length, balloon nominal pressure, balloon rated burst pressure and end hole diameter are the same as those of the PROTEUS™ PTA Balloon Catheter (K111750).

The embolic capture technological characteristics of the PROTEUS™ PTA Balloon Catheter are identical to those of the PROTEUS™ PTA Balloon Catheter (K111750). In both devices, the containment and removal of embolic material is achieved by proximal vessel occlusion, by means of an inflatable balloon, and subsequent capture and removal of embolic material.

Summary of Non-Clinical Testing

In vitro bench testing of the Angioslide PROTEUS™ PTA Balloon Catheter was conducted in accordance with Angioslide's Risk Analysis and all applicable FDA Guidance documents and ISO standards, including:

ISO 10555-1 – Sterile, Single Use Intravascular Catheters- Part 1: General Requirements

ISO 10555-4 – Sterile, Single Use Intravascular Catheters- Part 4: Balloon Dilatation Catheters

FDA Guidance – Non-Clinical Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems , January 13, 2005

FDA Guidance – Coronary and Carotid Embolic Protection Devices - Premarket Notification [510(k)] Submissions, February 15, 2008

All bench testing, unless otherwise specified, was conducted using finished devices which were sterilized by the final validated sterilization process.

Design Verification and Validation:

Design verification and validation testing of the PROTEUS™ PTA Balloon Catheter was performed using a "four corners" approach (i.e. 2 x 2 factorial of the largest and smallest balloon diameters and lengths. In addition to these four sizes, a middle catheter size was tested to provide supplemental data to support the robustness of the overall design of the Angioslide PROTEUS™ PTA Balloon Catheter. Sample sizes used for Design Verification and Validation testing were based on required confidence/reliability levels as a result of risk analysis performed for the PROTEUS™ PTA Balloon Catheter, or per recommendations within the FDA Guidance "Non-Clinical Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems." Specifically, the number of samples utilized for each test depended on whether the data to be collected was variable data or attribute data in nature.

PROTEUS™ PTA Balloon Catheter Design Verification and Validation Summary Table

Test Description	Accept/Reject Criteria	Results
Visual Inspection – External Surface	External surface of catheter effective length, including the distal end, is free from extraneous matter and surface defects **90% Confidence, 90% Reliability**	**PASS**
Visual Inspection – Distal Tip	Distal tip is smooth, rounded, tapered, or similarly finished. **90% Confidence, 90% Reliability**	**PASS**
Dimensional Inspection – Distal Bond O.D.	In Tolerance **90% Confidence, 90% Reliability**	**PASS**
Dimensional Inspection – Soft Tip Length	In Tolerance **90% Confidence, 90% Reliability**	**PASS**
Dimensional Inspection – Guidewire Inner Lumen	In Tolerance **90% Confidence, 90% Reliability**	**PASS**
Dimensional Inspection – Wrapped Balloon O.D.	The balloon must pass aperture < 2.00mm at 37deg C **90% Confidence, 90% Reliability**	**PASS**
Dimensional Inspection – Catheter Overall Length	In tolerance **90% Confidence, 90% Reliability**	**PASS**
Dimensional Inspection - Catheter Overall Effective Length	In tolerance **90% Confidence, 90% Reliability**	**PASS**
Dimensional Inspection - Knob Height	In tolerance **90% Confidence, 90% Reliability**	**PASS**
Handle Assembly Burst	Burst Pressure ≥ 12 atm **90% Confidence, 90% Reliability**	**PASS**
Handle Assembly Fatigue	≥ 10 Inflation/Deflation Cycles to RBP **95% Confidence, 90% Reliability**	**PASS**

Test Description	Accept/Reject Criteria	Results
Handle Assembly Leakage	No Leakage **90% Confidence, 90% Reliability**	**PASS**
Balloon Inflation and Deflation Time	No leakage during inflation Inflation Time: ≤ 14.0 sec, Deflation Time: ≤ 30.6 sec **90% Confidence, 90% Reliability**	**PASS**
Tensile Strength – Distal Balloon to Inner Shaft (Peel)	Force at Break ≥ 10N **90% Confidence, 95% Reliability**	**PASS**
Tensile Strength – Distal Balloon to Inner Shaft (Shear)	Force at Break ≥ 10N **90% Confidence, 95% Reliability**	**PASS**
Tensile Strength – Outer Shaft to T Connector:	Force at Break ≥ 10N **90% Confidence, 90% Reliability**	**PASS**
Tensile Strength – Inflation Tube to T Connector:	Force at Break ≥ 15N **90% Confidence, 90% Reliability**	**PASS**
Tensile Strength – Inflation Tube to Inflation Luer	Force at Break ≥ 15N **90% Confidence, 90% Reliability**	**PASS**
Tensile Strength – Cylinder to T Connector	Force at Break ≥ 15N **90% Confidence, 90% Reliability**	**PASS**
Tensile Strength – Inner Shaft to Pulling Rod	Force at Break ≥ 10N **90% Confidence, 95% Reliability**	**PASS**
Tensile Strength – Pulling Rod to Proximal Luer	Force at Break ≥ 15N **90% Confidence, 90% Reliability**	**PASS**
Tensile Strength – Pulling Rod to Knob Base	Force at Break ≥ 15N **90% Confidence, 90% Reliability**	**PASS**
Tensile Strength – Distal Cap to Shells	Force at Break ≥ 15N **90% Confidence, 90% Reliability**	**PASS**
Tensile Strength – Proximal Cap to Shells	Force at Break ≥ 15N **90% Confidence, 90% Reliability**	**PASS**

Test Description	Accept/Reject Criteria	Results
Tensile Strength – Knob Base to Knob Cover	Force at Break ≥ 15N **90% Confidence, 90% Reliability**	**PASS**
Corrosion Resistance	No signs of corrosion after treatment	**PASS**
Stroke Length	Minimum Stroke Length: ≥ 70% of the associated Balloon Working Length Maximum Stroke Length: Balloon can be deflated after reaching stroke limit. **90% Confidence / 90% Reliability**	**PASS**
Simulated Use in Tortuous Anatomy Model – guidewire compatibility	Catheter can be mounted over a .035" guidewire **90% Confidence, 90% Reliability**	**PASS**
Simulated Use in Tortuous Anatomy Model – Advance/Retract/ Deploy/Fold Balloon/ Withdraw after Procedure	Completely folded balloon passes through identified Introducer Sheath at the end of procedure. **90% Confidence, 90% Reliability**	**PASS**
Simulated Use in Tortuous Anatomy Model – Kink Resistance	No permanent deformations (kinks) are present once removed from the tortuous anatomy model. **90% Confidence, 90% Reliability**	**PASS**
Flow Characteristics	Distal flow observed in uninflated and deflated state, occlusion of distal flow in inflated state (straight and bend configurations) **90% Confidence, 90% Reliability**	**PASS**
Labeling Validation	Instructions for performing type 1 and type 2 recovery methods can be performed successfully per instructions.	**PASS**

Test Description	Accept/Reject Criteria	Results
Packaging Validation – Pouch Label Visual Inspection	Label is securely attached to the pouch surface. Across entire label, details/print is legible and free of smudging or creasing **90% Confidence, 90% Reliability**	**PASS**
Packaging Validation – Pouch Seal Visual Inspection	Pouch Seals at locations A, B, and C are visibly free of wrinkles, channels, visible bubbles, foreign material, transparent areas, and non-uniform seal width. **90% Confidence, 90% Reliability**	**PASS**
Packaging Validation – Bubble Leak Testing	No leaks are observed from seals or surface of the pouch. **90% Confidence, 90% Reliability**	**PASS**
Packaging Validation – Seal Strength Testing	Contract Manufacturer and Supplier Seal: Peel Force $\geq$ 5.0N **90% Confidence, 90% Reliability**	**PASS**

Biocompatibility Testing:

Based on Risk Analysis no additional biocompatibility testing was required for this modification.

Sterilization:

The PROTEUS™ PTA Balloon Catheter is packaged and sterilized using substantially equivalent materials, methods, and sterilization parameters used for most commercially available PTA balloon catheter products. The PROTEUS™ PTA Balloon Catheter is sterilized by ethylene oxide (EtO) sterilization providing a Sterility Assurance Level (SAL) of $1x10^{-6}$. EtO sterilization validation was completed in accordance with ISO 11135 "Medical devices – Validation and routine control of ethylene oxide sterilization". Testing of EtO residuals was performed in accordance with ISO 10993-7 "Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals." Results of the sterilization validation were found to meet all acceptance criteria and confirmed a SAL of $1x10^{-6}$, and EtO/ECh residuals were found to be within the ISO 10993-7 standard specification.

Packaging:

Packaging validation testing was conducted on the PROTEUS™ PTA Balloon Catheter packaging which included visual inspection (per ASTM F1886), leak testing (per ASTM F2096/ASTM F1929), and pouch seal strength testing (per ASTM F88). Prior to the start of packaging integrity testing, all samples were pre-conditioned by sterilization and subjected to transportation simulation per ASTM D4332-01 and ASTM D4169 respectively. All results of the packaging validation testing were found to meet acceptance criteria.

Pyrogenicity:

The PROTEUS™ PTA Balloon catheter is non-pyrogenic based successful completion of pyrogenicity testing:

Description of the method used to make the determination:	The Limulus amebocyte lysate (LAL) test is used for detection and quantification of bacterial endotoxin on each lot prior to release.
Identification of the testing endpoint reached and rationale for selecting that endpoint:	Must meet spec of 0.5 EU/ml for general blood contacting medical devices
Description of the extraction technique used to obtain the test fluid from the test device:	Flow through method, volume of LAL water used: 40ml/device
Identification of the reference method used:	FDA Guideline on Validation of the Limulus Amebocyte Lysate (LAL) Test as an End-Product Endotoxin Test, Dec 1987, USP <85> Bacterial Endotoxins Test

Shelf Life:

The PROTEUS™ PTA Balloon Catheter is currently validated for a three (3) year shelf life. After sterilization and accelerated aging, device function and performance verification/validation testing was conducted on the PROTEUS™ PTA Balloon Catheter and its packaging system that included the following:

- **Device**
  - Visual Inspection
  - Dimensional Inspection
  - Balloon Burst Pressure Testing
  - Balloon Fatigue Testing
  - Balloon Compliance Testing
  - Balloon Inflation/Deflation Testing
  - Catheter Leakage Testing
  - Bond Tensile Strength Testing
  - Simulated Use Testing
  - Stroke Length Testing
  - Flow Characteristics Testing
  - Corrosion Resistance Testing
- **Packaging**
  - Visual Inspection (per ASTM F1886)
  - Leak Testing (per ASTM F2096/ASTM F1929)
  - Pouch Seal Strength Testing (per ASTM F88)

The results of the testing described above were found to meet all acceptance criteria, and demonstrate that the PROTEUS™ PTA Balloon Catheter and its packaging system meets all functional and performance specifications at the end the product's three year shelf-life. Accelerated aging results are being confirmed through real time aging studies.

Substantial Equivalence Conclusion:

Non-clinical verification and validation of the PROTEUS™ PTA Balloon Catheter was performed through extensive bench testing, sterilization, packaging and shelf life testing. Results of the testing demonstrated that the PROTEUS™ PTA Balloon Catheter design met all specifications and is adequate for its intended use. Additionally, the test results demonstrated substantial equivalence of the PROTEUS™ PTA Balloon Catheter to its predicate device.

In conclusion, the PROTEUS™ PTA Balloon Catheter with Embolic Capture Feature is substantially equivalent in intended use, technological characteristics, safety, and performance characteristics to the following legally marketed predicate device:

- PROTEUS™ PTA Balloon Catheter with Embolic Capture Feature, Angioslide – K111750

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN - 8 2012

Angioslide
c/o Clay Anselmo
CEO
Reglera, LLC
11925 West I-70 Frontage Road North
Suite 900
Wheat Ridge, CO 80033

Re: K120164
Trade/Device Name: PROTEUS PTA Balloon Catheter with Embolic Capture Feature
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT, DQY
Dated: May 11, 2012
Received: May 14, 2012

Dear Mr. Anselmo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. However, we remind you that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

M S Hillebren

for Bram Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Indications for Use

510(k) Number (if known): K120164

Device Name: PROTEUS™ Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter with Embolic Capture Feature

Indications for Use:

The Angioslide PROTEUS™ Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter with Embolic Capture Feature is indicated for peripheral transluminal angioplasty and for capture and containment of embolic material during angioplasty, for the femoral, iliac, ilio-femoral, popliteal, tibial, peroneal, and profunda arteries.

The Angioslide PROTEUS™ PTA Balloon Catheter with Embolic Capture Feature is not intended for use in the renal, cerebral, coronary or carotid vasculature.

Prescription Use ___X___ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K120164